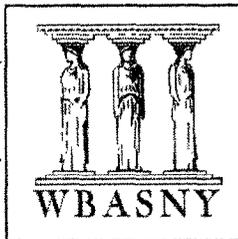


Women's Bar



Association

OF THE STATE

OF NEW YORK

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November 1, 2005

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0345
RIN No. 0910-AF72

**Drug Approvals: Circumstances Under Which an Active Ingredient May Be
Simultaneously Marketed in Both a Prescription Drug Product and an
Over-The-Counter Drug Product**

The Women's Bar Association of the State of New York ("WBASNY") is a statewide organization with over 3,500 members across the State. Our mission is not only to promote the status of women in the legal profession, but also to promote the fair and equal administration of justice for all women at the state, national and international level. We submit this letter in response to the request of the Food and Drug Administration ("FDA") for comments in its Advance Notice of Proposed Rulemaking. The FDA requested comments after receipt of the application of Duramed Research, Inc. The Company's application requested permission to market emergency contraception ("Plan B") over the counter to women who are 16 years of age and older, and by prescription to women under 16 years of age.

Women's health issues are a primary focus and concern to our bar association. We believe that proper and safe access to emergency contraception to avoid unwanted pregnancy is crucial. WBASNY therefore supports making Plan B as widely available at the counter as possible to women of childbearing age with appropriate safeguards and instructions as to use.

It has been estimated that emergency contraception could prevent over a million unwanted pregnancies and thousands of abortions annually in the United States alone. WBASNY has supported legislation proposed in New York State (A.116 Paulin/ S.3661 Spano, currently tabled) that would allow New York State

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pharmacists (and registered nurses) to dispense emergency contraception to women of childbearing age without a patient specific prescription. This legislation requires that, in dispensing emergency contraception, a licensed pharmacist who has been trained about emergency contraception follow written procedures and protocols. It also requires that the patient be provided with a fact sheet containing clinical considerations, methods for use, the need for follow up care, and referral information. We suggest the development of comparable or equivalent safeguards to the extent possible on the federal level for over the counter use of Plan B by women. Such safeguards might address many of the FDA's concerns about inappropriate use by teenagers. This would allow the FDA to consider permitting access by teenagers to Plan B over the counter as a means of reducing unwanted pregnancy and abortion rates among teenagers.

With regard to the specific pending application of Duramed Research, Inc., we believe that the FDA should take whatever actions are necessary to deal with the legal and practical problems involved in approving the application. We caution against imposition of requirements as to age identification or sworn statements verifying age at the counter. Since studies have shown that the health risk involved in use of emergency contraception pills ("ECP's") by adolescents is small,¹ we believe that the theoretical danger of a few adolescents potentially obtaining the drug without a prescription would be far outweighed by the advantages of adult women's ability to access it promptly in an emergency.

In summary, we recommend the approval of the proposal made by Duramed Research, Inc. as a positive first step toward allowing Plan B to be marketed with appropriate safeguards and instructions as to use to women of childbearing age without a prescription. Should you have any questions or concerns, please do not hesitate to contact me. Thank you for considering our comments.

Respectfully submitted,

Andrea Phoenix

Andrea Phoenix
President, WBASNY

¹See Melissa Schorr, *Emergency Contraception Safe for Use in Teenage Girls*, Medscape Medical News (Nov. 18, 2003) cited by Planned Parenthood at <http://www.plannedparenthood.org/pp2/portal/files/portal/medicalinfo/ec/fact-emergency-contraception.xml> : "ECPs can also be safely used by adolescents. One study designed to evaluate the safety of ECP use in teenagers enrolled 55 teens between the ages of 13 and 16. ECPs were found to be safe and well tolerated by the teens. The teens took the medicine properly, and they returned to their normal menstrual period at the same rate as adult women taking ECPs."